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R DANNY HUNTINGTON
BURNS DOANE SWECKER & MATHIS
PO BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER	
MARSCHEL, A	
ART UNIT	PAPER NUMBER
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Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).
- ☒ Applicant's response to the final rejection, filed 12/10/97 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. ☒ They raise new issues that would require further consideration and/or search. (See Note).
- c. ☐ They raise the issue of new matter. (See Note).
- d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. ☒ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: the "interphase" target material limitation is a new issue that would require further consideration and/or search, as well as the "40KB" limitation being a new issue.

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. ☒ Upon the filing of ~~an appeal~~, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: none

Claims objected to: none

Claims rejected: 1

However;

☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The ~~affidavit, exhibit or request for reconsideration~~ REMARKS have has been considered but does not overcome the rejection because of the above non-entirety of the amend, filed 12/10/97, and discussed further as attached.
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

- ☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.
- ☐ Other

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Further Explanation of Item 4 on the attached Advisory Action:

The second paragraph rejection is maintained due to the noted non-entry of the proposed amendment. It is acknowledged that the claim 1 amendment in line 3 therein with the arguments of applicants would have overcome this rejection.

The second paragraph rejection is maintained based on a lack of clear metes and bounds regarding hybridization conditions. Applicants argue that staining conditions are set forth in the specification or well known in the art and need not be in the claims. This is non-persuasive for two reasons. Firstly, the claim is unclear not regarding what is stained but what is "not" stained. As written the claims cite only target material but lack any description of what constitutes non-target material that would be unstained during the practice of the instant invention. The staining of all chromosomal material or a large portion of it is well known in the art whereas staining "only" a particular target material is known in the art as at least somewhat problematic, especially where a very lengthy or complex probe is utilized as instantly claimed. It is noted that relatively short probes of less than a few KB or even oligomers are the commonly utilized probes in the art. Therefore, the hybridization conditions must be carefully controlled for proper staining results. The instant claims lack definition of the appropriate metes and bounds of these critical hybridization conditions.

Applicants argue against the Weissman et al. 103(a) rejection by alleging that the reference lacks suggestion or disclosure of assaying for gene rearrangements. In response, Weissman et al. in column 2, lines 16-20, motivates the analysis of rearrangements of marker genes in cancer study and goes on thereafter at length to describe the invention as directed to localization of various gene segments which clearly suggests the instant rearrangement invention. The chromosome 3/17 rearrangement given in claim 1 is well known in the prior art from other analysis methods. It is lastly acknowledged that Weissman et al. does not disclose chromosomal labeling wherein the target material is interphase chromosomal material.

The obviousness-type double patenting rejection is maintained and noted as not argued by applicants.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee

for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unseccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

January 9, 1998

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800